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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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1632

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DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/864,364

Applicant(s)

SONE ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,7,9-19 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9-19 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The amendment and 1.132 Declaration filed on Mar 21, 2003 have been entered and assigned as Paper #15.

Claims 1, 10, 18, 24, and 25 have been amended. Currently, claims 1-5, 7, 9-19, and 21-25 are pending and under examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in paper #15 would be addressed to the extent that they apply to the current rejection.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 9-19, 21-24, and 25 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record and following.

In paper #15, applicants argue that Fodstad et al acknowledged that during last decade an increasing number of success have been seen for spontaneous and experimental human tumor metastasis, and the specification teaches SCID mice and nude rat. Therefore, the claimed invention is fully enabled.

The arguments are fully considered but found not persuasive because the teaching of *Fodstad et al* and achievement in the art since are limited to

immunodeficient nude rat and SCID mice, while claim recitation, "immunodeficient" is not limited to such, it encompasses any level or state (temporary or permanent) of an immunodeficient condition, whereas the establishment of a rodent bone metastasis model require profound immunocompromised state in the rodent.

In paper #15, applicants argue that claims do not recite "*any* cancer or tumor cells", instead, claims recite, "tumor cells that induce bone metastasis". Applicants also argue that the specification teaches using PTHrP to identify tumor cells that induce bone metastasis.

The argument has been fully considered but found not persuasive because claim recitation, "tumor cells that induce bone metastasis" encompasses *any* and *all* tumors that are metastatic, and not even limited to human lung or breast tumors that may be determined by the levels of PTHrP. An adequate guidance for practicing the invention requires more than a mere statement that it is part of the invention. Tumor cells in the claimed method are essential materials for practicing the invention. It is not sufficient to define the tumor cells solely by its principal biological property, i.e. "capable of inducing bone metastasis", because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any tumor cell with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all tumors that could be used to achieve a result without defining what means will do is not in compliance with the standard set forth under 35 U.S.C. § 112, 1<sup>st</sup> paragraph. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25

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USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). For example, the specification teaches that out of eight different types of human lung cancer cell lines, only the SBC-5 developed metastatic colonies in bone and other organs. Thus, the applicant was not successful in creating such a metastatic model with any human lung cancer cells, let alone other cancer cell types. *Engelbraaten et al* (Int J Cancer 1999;82:219-25) teach that two lines of breast cancer cells, MT-1 and MA-11, produced different pattern of tumor metastasis in a nude rat model, only MT-1 but not MA-11 leads to bone/bone marrow metastasis (section bridging left and right columns, page 221). Therefore, undue experiments are required for the skill in the art intending to practice the invention as it is now broadly claimed.

For reasons of record and set forth foregoing, the instant specification fails to meet the statutory enablement requirement set forth under 35 U.S.C. §112, 1<sup>st</sup> paragraph.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of claims 1, 3-10, 12, and 19-25 under 35 U.S.C. 102(b) as being anticipated by *Namikawa et al* (US 5,643,551) is withdrawn in view of the claim amendment.

The prior rejection of claims 1-5, 7, 9-19, and 21-25 under 35 U.S.C. 102(b) as being clearly anticipated by *Miki et al* ((Oncol Res 2000 12(5):209-17)) is withdrawn in view of the 1.132 Declaration.

Claims 1, 2, 4, 5, 10, 11, 24, and 25 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Engebraaten et al* (Int J Cancer 1999;82:219-25).

In paper #15, applicants argue that Engebraaten et al use intracardial injection, which is not peripheral administration.

The arguments have been fully considered but found not persuasive. This is because the specification defines the "peripheral administration" as "includes intravenous, intramuscle, intracutaneous, subcutaneous, and intraperitoneal administrations, and does not include percutaneous, inhalation, intracerebral, and ophthalmic administrations" (Specification, page 8). The specification does not exclude the intracardial injection as peripheral administration. Moreover, when considering the tumor cells injected into the cardiac ventricle would flow into veins rapidly, as does using intravenous injection. Thus, *Engebraaten et al* anticipate the instant claims.

Claims 1, 4, 5, 7, 9, 10, 13-15, and 21-25 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by *Sawyers et al* (US 6,365,797).

In paper #15, applicants argue that Sawyers itself distinguishes between the use of biopsy tissue and the use of cell suspensions, and in instances where Sawyer

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discusses injection of single cell suspensions, cells are injected directly into the bone marrow or directly into the prostate, they are not injected peripherally.

The arguments are fully considered but they are not persuasive.

First, Applicants have not particularly pointed out where in the cited patent that Sawyers distinguishes the tissue from cell in tumor inoculation. Secondly, the claims are not limited to administering cell suspension. Thirdly, Sawyers teaches both inoculating chunk tumor tissue and cell suspensions (See figure 5) by subcutaneous injection. Fourthly, applicants ignore the fact cited in the previous Office action that Sawyers uses subcutaneous administration (inoculation), which meets the definition in the specification for peripheral administration. *Sawyers et al* clearly teach establishing a SCID mouse model for bone metastasis using human prostate cancer LAPC-4 cells by subcutaneous inoculation (e.g. column 23, lines 16-17), the mice subsequently developed consistent bone/bone marrow metastases in addition to lymph and pulmonary metastasis tumors, wherein an enhanced frequency of bone metastasis was observed in a subset of the mice pretreated with a combination of radiation and NK cell depletion (column 24, lines 31-35). Therefore, *Sawyer et al* anticipate the instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, and 16-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Sawyers et al* (US 6,365,797), and in view of *Yano et al* (Intl J Cancer 1996;67:211-17).

In paper #15, applicants' argument relied on the assertion that *Sawyers* fails to teach a method for bone metastasis by peripheral injection of tumor cells, which has been addressed above, and will not be reiterated here.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.


Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
June 2, 2003

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal stroke extending to the right.